PATENTS

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:	Tracy A. Willson, et al.	**Examiner:**	Nirmal S. Basi
Serial No.:	09/688,286	**Art Unit:**	1646
Filed:	October 13, 2000	**Docket:**	11373A
For:	A NOVEL HAEMOPOIETIN RECEPTOR AND GENETIC SEQUENCES ENCODING SAME	**Dated:**	September 16, 2002

Assistant Commissioner for Patents
Washington, D.C. 20231

PETITION TO MAKE SPECIAL BECAUSE OF ACTUAL INFRINGEMENT UNDER 37 C.F.R. § 1.102

Applicants hereby petition to make this application special because of actual infringement.

Accompanying this petition is:

(a) a Statement of Facts in Support of the Petition to Make Special Because of Actual Infringement;

(b) a Statement by an Attorney in Support of the Petition to Make Special Because of Actual Infringement.

CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.8(a)

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to the Assistant Commissioner of Patents and Trademarks, Washington, D.C. 20231 on September 16, 2002.

Dated: September 16, 2002

Michelle Mustafa

Attached is a check in the amount of $130.00 pursuant to 37 C.F.R. § 1.17(h).

A duplicate of this paper is enclosed.

Respectfully submitted,

Peter I. Bernstein
Registration No. 43,497

Scully, Scott, Murphy & Presser
400 Garden City Plaza
Garden City, NY 11530
(516) 742-4343

PIB/ZY:sf

Enclosures
Statement by attorney in support of Petition
Statement of Facts
Petition Fee
Exhibit A

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STATEMENT OF FACTS IN SUPPORT OF PETITION TO MAKE SPECIAL BECAUSE OF ACTUAL INFRINGEMENT

I, Peter I. Bernstein, am an attorney registered to practice before the United States Patent and Trademark Office and I hereby make the following statement:

There is apparently actual infringement of the claimed invention. Specifically, the pending claims are drawn to an antibody to recombinant human IL-13 Rα1.

The applicants have discovered that R&D Systems, Inc., 1614 McKinley Place, N.E., Minneapolis, MN 55413 ("R & D"), is apparently selling antibodies to human IL-13 Rα1. From the information available on the attached product data sheet (Exhibit A), the applicants believe that claims 18-19 of the present invention are infringed.

Upon information and belief, R & D is selling and has sold antibodies to human IL-13 Rα1 since at least August, 2001. Based on the attached commercial offer for sale of the apparently infringing product and based on a careful and thorough search of the prior art, I hereby state that, upon information and belief, claims 18 and 19 in the present application are unquestionably infringed.

CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.8(a)

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to the Assistant Commissioner of Patents and Trademarks, Washington, D.C. 20231 on September 16, 2002.

The product that appears to infringe the claims of this invention was first discovered to exist on or about July 3, 2002.

Respectfully submitted,

Peter I. Bernstein
Registration No. 43,497

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Garden City, NY 11530
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STATEMENT IN SUPPORT OF PETITION TO MAKE SPECIAL BECAUSE OF ACTUAL INFRINGEMENT

I, Peter I. Bernstein, make the following statements:

1. I have made a rigid comparison of the apparently infringing acts referred to in my accompanying statement with the claims in this invention.

2. In my opinion and upon information and belief claims 18 and 19 are unquestionably infringed.

CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.8(a)

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to the Assistant Commissioner of Patents and Trademarks, Washington, D.C. 20231 on September 16, 2002.

3. I have made a search of the pertinent prior art. All such material art is of record in an Information Disclosure Statement submitted to the U.S. patent and Trademark Office October 13, 2000.

4. I believe that all the pending claims in this application are allowable.

Respectfully submitted,

Peter I. Bernstein
Registration No. 43,497

Scully, Scott, Murphy & Presser
400 Garden City Plaza
Garden City, NY 11530
(516) 742-4343

PIB/ZY:sf

R&D SYSTEMS

Anti-human IL-13 Rα1 Antibody

ORDERING INFORMATION

Catalog Number: AF152

Lot Number: DVK02

Size: 100 µg

Formulation: 0.2 µm filtered solution in PBS

Storage: -20° C

Reconstitution: sterile PBS

Specificity: rhIL-13 Rα1 extracellular domain

Immunogen: NS0-derived rhIL-13 Rα1 extracellular domain

Ig Type: human IL-13 Rα1 extracellular domain specific goat IgG

Applications: Neutralization of Bioactivity
ELISA
Western blot

Preparation
Produced in goats immunized with purified, NS0-derived, recombinant human interleukin 13 receptor alpha 1 (rhIL-13 Rα1) extracellular domain. IL-13 Rα1 specific IgG was purified by human IL-13 Rα1 affinity chromatography.

Formulation
Lyophilized from a 0.2 µm filtered solution in phosphate-buffered saline (PBS).

Endotoxin Level
< 10 ng per 1 mg of the antibody as determined by the LAL method.

Reconstitution
Reconstitute with sterile PBS. If 1 mL of PBS is used, the antibody concentration will be 0.1 mg/mL.

Storage
Lyophilized samples are stable for greater than six months when held at -20° C to -70° C. Upon reconstitution, the antibody can be stored at 2° - 4° C for at least 1 month without detectable loss of activity. Reconstituted antibody can also be aliquotted and stored frozen at -20° C to -70° C for at least six months without detectable loss of activity. **Avoid repeated freeze-thaw cycles.**

Specificity
This antibody has been selected for its ability to neutralize rhIL-13 Rα1 bioactivity. In direct ELISAs and Western blots, this antibody shows less than 5% cross-reactivity with rhIL-13 Rα2, rmIL-13 Rα1, rhIL-5 Rα, rhIL-5 Rβ, rhIL-4 R, and rhIL-9 R.

Neutralization of Human Interleukin 13 Bioactivity
The exact concentration of antibody required to neutralize rhIL-13 activity is dependent on the cytokine concentration, cell type, growth conditions and the type of activity studied. To provide a guideline, R&D Systems has determined the neutralization dose for this antibody under a specific set of conditions. The **Neutralization Dose$_{50}$ (ND$_{50}$)** for this antibody is defined as that concentration of antibody required to yield one-half maximal inhibition of the cytokine activity on a responsive cell line, when that cytokine is present at a concentration just high enough to elicit a maximum response.

The ND$_{50}$ for this lot of anti-human IL-13 Rα1 antibody was determined to be approximately 10 - 30 µg/mL in the presence of 10 ng/mL of rhIL-13, using the factor-dependent human cell line. The specific conditions are described in the figure legends.

Additional Applications
For direct ELISAs, the antibody can be used at 0.5 - 1.0 µg/mL with the appropriate secondary reagents to detect human IL-13 Rα1. The detection limit for rhIL-13 Rα1 is approximately 0.25 ng/well.

For western blot analysis, the antibody can be used at 0.1 - 0.2 µg/mL with the appropriate secondary reagents to detect human IL-13 Rα1. The detection limit for rhIL-13 Rα1 is approximately 5 ng/lane under non-reducing and reducing conditions.

Optimal dilutions should be determined by each laboratory for each application.

R&D Systems, Inc.
1-800-343-7475

Figure 1

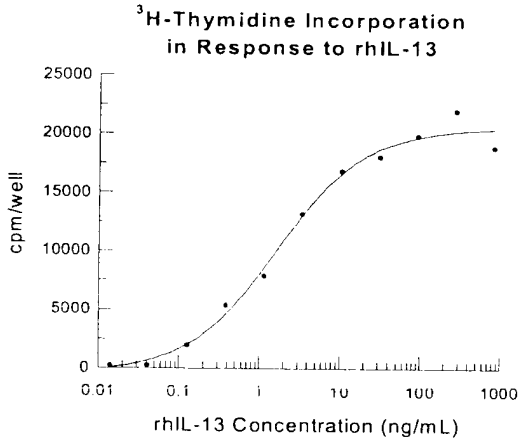

Figure 2

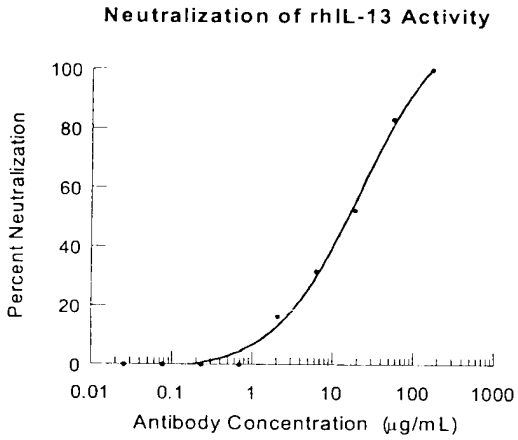

Figure 1
Human IL-13 stimulates the ^{3}H-thymidine incorporation by human TF-1 cells in a dose-dependent manner (Kitamura, T. *et al.*, 1989, J. Cell Physiol. **140(2)**:323 - 334). The ED_{50} for this effect is typically 3.0 - 6.0 ng/mL.

Figure 2
Typical data for anti-human IL-13 is shown in Figure 2. To measure the ability of the antibody to neutralize the bioactivity of rhIL-13 on human TF-1 cells, TF-1 cells were incubated with various concentrations of the antibody for 1 hour at 37° C in a 96 well plate. Following this preincubation period, rhIL-13 was added. The assay mixture in a total volume of 100 μL, containing antibody at the concentrations indicated, rhIL-13 at 10 ng/mL and cells at 1 x 10^5 cells/mL, was incubated at 37° C for 48 hours in a humidified CO_2 incubator. ^{3}H-thymidine was added during the final 4 hours of incubation. The cells were subsequently harvested onto glass fiber filters and the ^{3}H-thymidine incorporated into DNA was determined. The ND_{50} of the antibody under these conditions is approximately 10 - 30 μg/mL.